Attorney Docket No.: AVIG-024/01US (formerly 0800-0024) **PATENT**

Express Mail Label Number: EV 151700733 US
Date of Deposit: February 12, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, Washington, DC 20231.

Date: 2-12-03 By: Hanna Hacham
Hanna Hacham

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE #9/R.T. 2/21

In Re Application of:

KATHERINE A. HIGH

Confirmation No.: 5537

Serial No.: 09/880,702

Art Unit: 1635

Filing Date: June 13, 2001

Examiner: B. Whiteman

ELECT. A

Title: METHODS FOR ADMINISTERING RECOMBINANT ADENO-ASSOCIATED VIRUS VIRIONS TO HUMANS PREVIOUSLY EXPOSED TO ADENO-ASSOCIATED VIRUS

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO REQUIREMENT FOR RESTRICTION AND SPECIES ELECTION REQUIREMENT

Sir:

This is in response to the Restriction Requirement dated September 27, 2002, with a shortened period of one-month for response. Accordingly, an extension of time is requested and a Petition and the fee therefor accompany this response.

The Examiner required election of one of the following two groups of claims for prosecution at this time:

Group I, claims 2 and 4; and

Group II, claim 3-26.

The Examiner also requested that applicants select a therapeutic polypeptide from the group of polypeptides listed on pages 11-12 of the application, should Group II be elected.

In response to the restriction requirement, applicants elect to proceed with the claims of Group II, claims 3-26, with traverse. Applicants note that claim 1 is considered a linking claim and that upon allowance of the linking claim, the restriction requirement as to the linked inventions will be withdrawn and that any claim(s) depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants expressly reserve their right under 35 USC §121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application.

In response to the species election requirement, applicants elect to proceed with Factor IX. The claims reading on the elected species are claims 1-26. It is to be understood that this election of species is for the purposes of preliminary search and examination only, and that upon allowance of a generic claim, applicants will be entitled to consideration of claims to the additional species.

Applicants traverse this restriction requirement for the following reasons. The Examiner, in Paper no. 7, states that the claims of Group I, claims 2 and 4, relate to methods using a "heterologous nucleic acid sequence encoding a non-therapeutic polypeptide." Office Action, page 2. The Examiner further states that claim 3 pertains to a method using a "heterologous nucleic acid sequence encoding a therapeutic polypeptide." Office Action, page 2. Applicants disagree. No such limitation is found in claims 2 and 4. It is true that claim 1 is not limited to the use of a nucleic acid sequence encoding a therapeutic polypeptide and claims 2 and 4 depend from claim 1. Thus, claims 2 and 4 are also not limited to the use of a nucleic acid sequence encoding a therapeutic polypeptide. However, neither is claim 3 so limited. Claim 3 recites: "The method of claim 1, wherein expression of said heterologous nucleic acid sequence results in a therapeutic effect." The claim simply does not recite the use of a nucleic acid sequence encoding a therapeutic polypeptide. A review of the application makes clear that nucleic acid sequences resulting in a therapeutic effect, such as antisense oligonucleotides, are also contemplated for use. See, e.g., page 12 of the application. Thus, claim 3 is not limited as specified by the Office.

Notwithstanding the above, applicants are amending claim 1 in the accompanying Preliminary Amendment to incorporate the recitations of claim 3. As explained above, claim 3, although reciting the use of a nucleic acid sequence resulting in a therapeutic effect, is not limited to the use of a nucleic acid sequence encoding a therapeutic protein.

Respectfully submitted,
COOLEY GODWARD LLP

Date: 2/12/03

By: _____
Roberta L. Robins
Reg. No. 33,208

Cooley Godward LLP
Attn: Patent Group
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2155
Tel: (650) 843-5000
Fax: (650) 857-0663

RLR/hh